

THE IDYLLA™ MENU

Gene content selected from relevant industry guidelines, key opinion leaders, and pharmaceutical research.

		Catalog # for solid biopsies	Catalog # for liquid biopsies
IVD Tests			
MSI 510(k) ¹	Microsatellite Instability detection at 7 MSI loci	 A0160/6	
RUO Assays²			
EGFR	51 mutations in EGFR exons 18, 19, 20 and 21	 A0061/6	
	49 mutations in EGFR exons 18, 19, 20 and 21		 A0111/6
GeneFusion	ALK, ROS1, RET, NTRK1/2/3 fusions & MET Exon 14 skipping	 A0121/6	
KRAS	21 mutations in KRAS exons 2, 3 and 4	 A0021/6	 A0081/6
NRAS-BRAF ³	23 mutations in NRAS exons 2, 3, 4 and BRAF exon 15	 A0031/6	 A0091/6
BRAF	7 mutations in BRAF exon 15	 A0011/6	
IDH1-2 ⁴	5 mutations in <i>IDH1</i> gene and 10 mutations in <i>IDH2</i> gene	 A0181/6 (Vial) A0191/6 (Cartridge)	
PIK3CA-AKT1	13 mutations in <i>PIK3CA</i> gene and 1 mutation in <i>AKT1</i> gene	 A0171/6	

(1) For in vitro diagnostic use.

For use on the Biocartis Idylla™ System only.

The Idylla™ MSI Test, for use on the Idylla™ System, uses formalin-fixed, paraffin-embedded (FFPE) tissue sections of human CRC tumor, from which nucleic acids are liberated, then analyzed using PCR amplification of seven monomorphic biomarkers (ACVR2A, BTBD7, DIDO1, MRE11, RYR3, SEC31A and SULF2) and subsequent melt-curve analysis. The Idylla™ MSI Test reports results as either microsatellite stable (MSS), or microsatellite instability high (MSI-H) or invalid.

The Idylla™ MSI Test is indicated for use by healthcare professionals for the qualitative identification of microsatellite instability (MSI) in colorectal cancer (CRC) tumors, indicative of mismatch repair deficiency, and as an aid in the identification of probable Lynch syndrome to help identify patients that would benefit from additional genetic testing to diagnose Lynch syndrome.

The results from the Idylla™ MSI Test should be interpreted by healthcare professionals in conjunction with other clinical findings, family history, and other laboratory data. The Idylla™ MSI Test should not be used for diagnosis of CRC.

The clinical performance of this device to guide treatment decision for MSI high patients has not been established.

(2) For Research Use Only. Not for use in diagnostic procedures.

(3) Included in the Idylla™ NRAS-BRAF-EGFR S492R Mutation Assay.

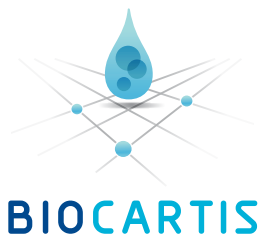
(4) The Idylla™ IDH1-2 Mutation Assay Kit consists of a Cartridge and a Vial.

THE IDYLLA™ SYSTEM. BUILT FOR YOUR NEEDS.

Idylla™ is a revolutionary, fully automated system that makes molecular testing convenient, affordable and fast.

Idylla™ delivers accurate results from a minimal amount of specimen and is suitable for any lab.





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Idylla™ MSI Test and Idylla™ System are cleared in the US under K211181.

Idylla™ GeneFusion Assay; Idylla™ IDH1-2 Mutation Assay Kit; and Idylla™ EGFR, KRAS, BRAF, NRAS-BRAF, PIK3CA-AKT1, ctEGFR, ctKRAS & ctNRAS-BRAF Mutation Assays are for Research Use Only; not for use in diagnostic procedures.

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Idylla™ is available for sale in Europe, the US and many other countries. Please check availability with a Biocartis representative.

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